

# Driving Home the Point: Over-the-Counter Medicines and Driving

FDA Basics – June 30, 2014

Ali Mohamadi, MD

Medical Officer

Professional Affairs and Stakeholder Engagement

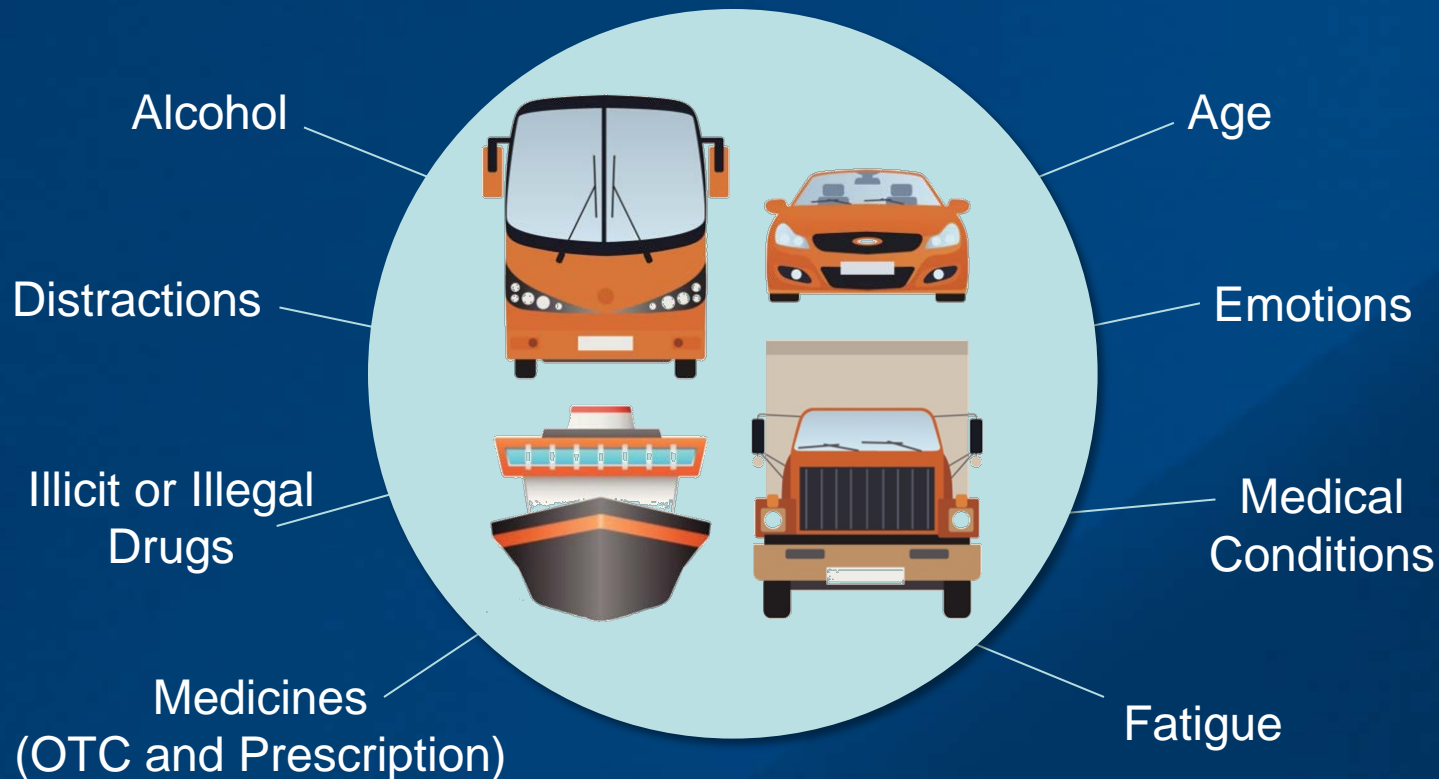
U.S. Food and Drug Administration  
Center for Drug Evaluation and Research



# Webinar Agenda

- Factors that can affect your ability to drive safely
- How some over-the-counter medicines can impair your ability to drive
- Reading labels on over-the-counter medicines (misconceptions and truths)
- How to use the label on over-the-counter medicines to see if it is safe to drive
- Examples of over-the-counter medicines and labels that have drowsiness or driving warnings

# Factors that Can Impair Your Driving



# Driving and OTC Medicine: Proceed Cautiously

Some of the ways medicines can affect your driving:

- Decrease attentiveness
- Impair judgment of time and distance
- Slow motor skills (reflexes)
- Add to effects of fatigue or lack of sleep (“drowsy driving”) and other causes of drowsiness



# The Ever-Expanding Marketplace





# Misconceptions About OTC Medicines and Labels

- OTC medicines don't have risks
- I can take OTC medicine any way and in any amount I want to without harm
- I don't need to read the label – I know all I need to know about the medicine
- My family and I have used the medicine before and we have never been harmed
- If some medicine is good, more is better

# The Truth About OTC Medicines and Labels

- OTC medicines are serious medicines and have risks. All medicines have risks. The risks increase if you don't use medicine as directed
- The ***Drug Facts*** label is on OTC medicines to help you choose carefully and use the medicine safely
- You have to read the label every time to use the medicine safely every time
- If you have any questions about your OTC medicine or OTC medicine labels, talk to your healthcare professional

# Over-the-Counter *Drug Facts* Label





# Drug Facts Label

## Drug Facts

### Active ingredient (in each tablet)

Chlorpheniramine maleate 2 mg

### Purpose

.....Antihistamine

**Uses** temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

### Warnings

**Ask a doctor before use if you have**

■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis  
■ trouble urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives**

**When using this product**

■ You may get drowsy ■ avoid alcoholic drinks  
■ alcohol, sedatives, and tranquilizers may increase drowsiness  
■ be careful when driving a motor vehicle or operating machinery  
■ excitability may occur, especially in children

**If pregnant or breast-feeding, ask a health professional before use.**

### Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

**Inactive ingredients** D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

# How to Check the Label to See if You Are Able to Drive

## Drug Facts

### Active ingredient (in each tablet)

Chlorpheniramine maleate 2 mg

### Purpose

Antihistamine

**Uses** temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- sneezing
- runny nose
- itchy, watery eyes
- itchy throat

## Warnings

### When using this product

- You may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

# When using this product:

- Drowsiness
  - Tiredness, drowsiness or dizziness may occur
  - You may get very drowsy
  - Drowsiness will occur
  - Marked drowsiness will/may occur, or may cause marked drowsiness
  - Do not take more than directed. Taking more than directed may cause drowsiness
- Motor vehicle and machinery impairment
  - Be careful (or use caution) when driving a motor vehicle or operating machinery
  - Do not drive a motor vehicle or operate machinery
- Other
  - Avoid alcoholic drinks
  - Alcohol, sedatives, and tranquilizers may increase drowsiness
  - Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor
  - May cause \_\_\_\_\_ - excitability, blurred vision, nausea, faintness, or confusion

# OTC Medicines That May Affect Your Ability to Drive

- Antihistamines –
  - temporarily relieve runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or other respiratory allergies
  - Temporarily relieve cough due to the common cold
  - Relieve occasional sleeplessness

Antihistamines can be combined with other active ingredients that relieve cough, reduce nasal congestion, or reduce pain and fever

- Some anti-diarrheals – which treat or control the symptoms of diarrhea
- Anti-emetics (motion sickness) – prevent and treat nausea, vomiting, and dizziness associated with motion sickness

# Antihistamines

## Drug Facts

### Active ingredient (in each 5 mL\*)

Diphenhydramine HCl 12.5 mg ..... Antihistamine

\* 5 mL = 1 teaspoonful

### Purpose

symptoms due to common cold: ■ runny nose ■ sneezing

due to an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis

**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers

**When using this product** ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery

**When using this product** ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children

children under 6 years

**DO NOT USE**

**Other information** Store at room temperature 15°-30°C (59°-86°F).

**Inactive ingredients** citric acid, D&C red no. 33, FD&C red no. 40, black cherry flavor, methylparaben, propylene glycol, propylparaben, saccharin sodium, sodium citrate, sorbitol, water.



# Antihistamine in Combination

**DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING**

<b>Drug Facts</b>	
<b>Active Ingredients (In each 15 mL tablespoon)</b>	<b>Purpose</b>
Dextromethorphan HBr 15 mg.....	Cough suppressant
Doxylamine succinate 6.25 mg.....	Antihistamine
<b>Uses</b> temporarily relieves cold symptoms: <input type="checkbox"/> cough <input type="checkbox"/> runny nose and sneezing	
conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. <input type="checkbox"/> to make a child sleepy	
<b>Ask a doctor before use if you have</b> <input type="checkbox"/> glaucoma <input type="checkbox"/> a breathing problem such as emphysema or chronic bronchitis <input type="checkbox"/> cough that occurs with too much phlegm (mucus) <input type="checkbox"/> trouble urinating due to an enlarged prostate gland <input type="checkbox"/> persistent or chronic cough as occurs with smoking, asthma or emphysema	
<b>When using this product</b> <input type="checkbox"/> do not use more than directed <input type="checkbox"/> excitability may occur, especially in children <input type="checkbox"/> marked drowsiness may occur <input type="checkbox"/> avoid alcoholic drinks <input type="checkbox"/> be careful when driving a motor vehicle or operating machinery <input type="checkbox"/> alcohol, sedatives and tranquilizers may increase drowsiness	

<b>Drug Facts (continued)</b>	
Stop use and ask a doctor if <input type="checkbox"/> cough lasts for more than 7 days, <input type="checkbox"/> headache that lasts,	
professional before use. <input type="checkbox"/> overdose, get medical help	
<input type="checkbox"/> use dose cup	
30 mL (2 TBSP) every 6 hours	
children 4 to under 12 years	ask a doctor
children under 4 years	do not use
<input type="checkbox"/> when using other Daytime or Nighttime products, carefully read each label to insure correct dosing	
<b>Other information</b> <input type="checkbox"/> each TBSP contains: sodium 15 mg <input type="checkbox"/> store at 20°-25°C (68°-77°F)	
<b>Inactive ingredients</b> alcohol, anhydrous citric acid, <input type="checkbox"/> flavor, high fructose corn syrup, polyethylene glycol, purified water,	
<b>For more information</b> call 1-800-632-6900	

# Antihistamine in Combination

Drug Facts	Drug Facts (continued)
<b>Active ingredients (in each caplet)</b> Diphenhydramine citrate 38 mg	<b>Purposes</b> Nighttime sleep aid
<b>Uses</b> <ul style="list-style-type: none"><li>■ for relief of occasional sleeplessness when associated with minor aches and pains</li><li>■ helps you fall asleep and stay asleep</li></ul>	
<ul style="list-style-type: none"><li>■ hives</li><li>■ facial swelling</li><li>■ asthma (wheezing)</li><li>■ shock</li><li>■ skin reddening</li><li>■ rash</li><li>■ blisters</li></ul> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Stomach bleeding warning:</b> This product contains an NSAID.</p>	<ul style="list-style-type: none"><li>■ kidney disease, or asthma</li><li>■ you are taking a diuretic</li><li>■ you have a breathing problem such as emphysema or chronic bronchitis</li><li>■ you have glaucoma</li><li>■ you have trouble urinating due to an enlarged prostate gland</li></ul>
<b>When using this product</b> <ul style="list-style-type: none"><li>■ drowsiness will occur</li><li>■ avoid alcoholic drinks</li><li>■ do not drive a motor vehicle or operate machinery</li><li>■ take with food or milk if stomach upset occurs</li><li>■ the risk of heart attack or stroke may increase if you use more than directed or for longer than directed</li></ul>	

# Anti-Diarrheal Medicines

## Drug Facts

**Active ingredient (in each caplet)**

**Purpose**

**Use** controls symptoms of diarrhea, including Travelers' Diarrhea

## Drug Facts (continued)

### Warnings

**Allergy alert:** Do not use if you have ever had a rash or other allergic reaction to loperamide HCl

**Do not use** if you have bloody or black stool

**Ask a doctor before use if you have**

■ fever ■ mucus in the stool ■ a history of liver disease

## When using this product

■ tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

**Stop use and ask a doctor if** ■ symptoms get worse ■ diarrhea lasts for more than 2 days ■ you get abdominal swelling or bulging. These may be signs of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

### Directions

■ **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**

■ find right dose on chart. If possible, use weight to dose; otherwise, use age.

adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
children 6-8 years (48-59 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
children under 6 years (up to 47 lbs)	ask a doctor

### Other information

■ store at 20°-25°C (68°-77°F) ■ **do not use if blister unit is broken or torn**

**Inactive ingredients** anhydrous lactose, camauba wax, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch

# DRIVING?

CHECK THE MEDICINE LABEL  
TO MAKE SURE YOU'RE ABLE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES • FOOD AND DRUG ADMINISTRATION



- Use the *Drug Facts* label to choose and use over-the-counter medicine safely
- Check all your medicine labels before you hit the road
  - Do they say anything about drowsiness?
  - Do they say anything about driving or operating machinery?
- Consider if you may be able to choose and use a different medicine that doesn't have those effects

# Additional Information

- Over-the-Counter Drug Facts Label - Video  
[https://www.youtube.com/watch?v=hT6Th\\_QfQKE](https://www.youtube.com/watch?v=hT6Th_QfQKE)
- Driving When You Are Taking Medications  
<http://www.fda.gov/drugs/resourcesforyou/ucm079514.htm>
- Some Medication and Driving Don't Mix  
<http://www.fda.gov/Forconsumers/ConsumerUpdates/ucm107894.htm>
- Allergy Meds Could Affect Your Driving  
<http://www.fda.gov/forconsumers/consumerupdates/ucm354117.htm>
- Medicines in My Home  
<http://www.fda.gov/medsinmyhome>



# FDA Basics

[http://www.fda.gov/aboutfda/  
transparency/basics/default.htm](http://www.fda.gov/aboutfda/transparency/basics/default.htm)



Email: [CDERPASE@fda.hhs.gov](mailto:CDERPASE@fda.hhs.gov)